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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,916

07/11/2006

Michelle Leanne Styles

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EXAMINER

WILLIS, DOUGLAS M

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

10/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,916	Applicant(s) STYLES ET AL.	
	Examiner DOUGLAS M. WILLIS	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-6 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08-17-09</u> . | 6) <input type="checkbox"/> Other: _____ |

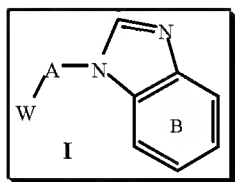
DETAILED ACTION

Status of the Claims

Claims 1-7 and 9 are pending in the current application. According to the *Amendments to the Claims*, filed October 9, 2009, claims 1 and 3 were amended and claims 8 and 10-13 were cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/AU2005/000022, filed January 12, 2005, which claims priority under 35 U.S.C. § 119(a-d) to AU 2004900103, filed January 12, 2004.

Status of Restrictions / Election of Species

Applicant's affirmation of the following election, without traverse, in the reply filed on



October 9, 2009, is acknowledged: a) Group I - claims 1-6, where A = -pyrazinyl, -pyrimidyl or -pyridyl; and Q = -a bond; and b) substituted benzimidazole of formula I - p. 40, example 20.

The requirement was made FINAL in the *Non-Final Rejection*, mailed on June 9, 2009.

This application contains claims 7 and 9, drawn to nonelected inventions, without traverse, in the reply filed on October 9, 2009. A complete reply to the final rejection may include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.02.

The sections of U.S.C. Title 35 that formed the basis of prior rejections formulated, as well as any references supporting said rejections, that are not included with this Office action, may be found in the *Non-Final Rejection*, mailed on June 9, 2009. Furthermore, any rejections or objections of record not explicitly addressed herein below, are hereby withdrawn, in light of applicant's arguments and/or the *Amendments to the Claims*, filed October 9, 2009.

Thus, a second Office action and prosecution on the merits of claims 1-6 is contained within.

Status of Claim Rejections - 35 U.S.C. § 103

Applicant's arguments, on pages 11-13 of the *Remarks*, filed October 9, 2009, with respect to claims 10-13, have been fully considered, but will not be discussed further, since, according to the *Amendments to the Claims*, filed October 9, 2009, claims 10-13 have been cancelled by applicant.

Applicant's arguments, on pages 11-13 of the *Remarks*, filed October 9, 2009, with respect to claims 1, 2 and 4-6, have been fully considered, but are not persuasive. Consequently, the rejection of claims 1, 2 and 4-6, made in the *Non-Final Rejection*, mailed on June 9, 2009, is hereby maintained for the reasons of record.

Applicant primarily argues that the instant invention is nonobvious over the prior art since the embodiments of Z are functionally different from the homolog incidentally described by Goulet in that they function as Michael acceptors and are able to react with a crucial cysteine residue in the kinase to be inhibited. Moreover, applicant further argues that the instant invention is nonobvious over the prior art since the present compounds are designed to be JAK inhibitors, while the Goulet compounds are designed to be Src inhibitors.

In response to applicant's arguments that the instant invention is nonobvious over the prior art since the embodiments of Z are functionally different from the homolog incidentally described by Goulet in that they function as Michael acceptors and are able to react with a crucial cysteine residue in the kinase to be inhibited, the examiner respectfully disagrees, since,

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if applicant intends to rely on unexpected or unforeseen results, attention is invited to MPEP § 716. Absent clear, convincing, side-by-side, data-demonstrating unobviousness vis-à-vis the prior art commensurate with the scope of protection sought, the claims are considered *prima facie* obvious.

Moreover, in response to applicant's arguments that the instant invention is nonobvious over the prior art since the present compounds are designed to be JAK inhibitors, while the Goulet compounds are designed to be Src inhibitors, the examiner further respectfully disagrees, since, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. {See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985)}.

Similarly, in response to applicant's arguments that the instant invention is nonobvious over the prior art since the present compounds are designed to be JAK inhibitors, while the Goulet compounds are designed to be Src inhibitors, a recitation of the intended use of the instantly recited substituted benzimidazoles of the formula I must result in a structural difference between the instantly recited substituted benzimidazoles of the formula I and Goulet's substituted benzimidazoles in order to patentably distinguish the instantly recited substituted benzimidazoles of the formula I from Goulet's substituted benzimidazoles. If Goulet's substituted benzimidazoles are capable of performing the intended use, then they meet the claim.

MPEP § 2144-I states that *the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill*

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in the art, established scientific principles, or legal precedent established by prior case law. {See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000); *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988); *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985); and *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993)}.

Likewise, in the chemical arts, it is widely accepted that *structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions or compounds, creates a prima facie case of obviousness.* {See *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, No. 06-1329, slip op. at 9 (Fed. Cir. June 28, 2007) (quoting *In re Dillon*, 919 F.2d 688, 692 [16 USPQ2d 1897] (Fed. Cir. 1990) (en banc)); and *In re Papesch*, 315 F.2d 381 [137 USPQ 43] (C.C.P.A. 1963)}. *The reason or motivation need not be an explicit teaching that the claimed compound will have a particular utility; it is sufficient to show that the claimed and prior art compounds possess a “sufficiently close relationship... to create an expectation, in light of the totality of the prior art, that the new compound will have similar properties to the old.* {See *In re Dillon*, 919 F.2d at 692; and *In re Wilder*, 563 F.2d 457, 460 [195 USPQ 426] (C.C.P.A. 1977)}.

Applicant should note that a *prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. {See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963); *In re*

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Wiechert, 370 F.2d 927, 152 USPQ 247 (CCPA 1967); and *In re Peterson*, 65 USPQ2d 1379 (Fed. Cir. 2003)}.

Since arguments of counsel cannot take the place of factually supported objective evidence in the record, an assertion of what seems to follow from common experience, which is merely deemed as attorney argument, is not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness. {See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984); *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)}. Rebuttal evidence may be appropriately submitted by way of an affidavit or declaration under 37 CFR 1.132.

Status of Claim Rejections - Obviousness-type Double Patenting

Applicant's arguments, on page 13 of the *Remarks*, filed October 9, 2009, with respect to claims 10-13, have been fully considered, but will not be discussed further, since, according to the *Amendments to the Claims*, filed October 9, 2009, claims 10-13 have been cancelled by applicant.

Applicant's arguments, on page 13 of the *Remarks*, filed October 9, 2009, with respect to claims 1, 2 and 4-6, have been fully considered, but are not persuasive. Consequently, the rejection of claims 1, 2 and 4-6, made in the *Non-Final Rejection*, mailed on June 9, 2009, is hereby maintained for the reasons of record.

Applicant primarily argues that a terminal disclaimer, with respect to copending application 10/581,412, has been submitted herewith, thus obviating the basis for rejection.

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In response to applicant's arguments that a terminal disclaimer, with respect to copending application 10/581,412, has been submitted herewith, thus obviating the basis for rejection, the examiner respectfully disagrees, since the terminal disclaimer submitted herewith has yet to be approved.

New Specification Objection - Abstract

Applicant is reminded of the proper content of an abstract of the disclosure.

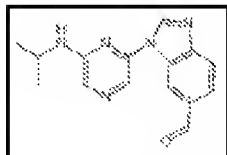
With regard particularly to chemical patents, for compounds or compositions, the general nature of the compound or composition should be given as well as the use thereof, e.g., *The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics.* Exemplification of a species could be illustrative of members of the class. For processes, the reactions, reagents and process conditions should be stated, generally illustrated by a single example, unless variations are necessary. See MPEP § 608.01(b), Section B.

The abstract of the disclosure is objected to because it fails to exemplify any members or formulae illustrative of its class. Correction is required. See MPEP § 608.01(b).

The examiner suggests incorporating the structure of formula I into the abstract, to overcome this objection.

New Claim Objections

Claim 3 is objected to because of the following informalities: the species, shown to the



left, is not a substituted benzimidazole of the formula I and thus lacks compliance with the *Requirement for Restriction / Election of Species*, mailed

on April 13, 2009. Appropriate correction is required.

Claim 4 is objected to because the recitation of an intended use for a compound must result in a structural difference in the compound, in order to be further limiting. In the instant claim, the intent is to use a substituted benzimidazole of the formula I, as an irreversible inhibitor of JAK-3 kinase. Since the intended use of a substituted benzimidazole of the formula I, as an irreversible inhibitor of JAK-3 kinase, fails to result in a structural difference to the substituted benzimidazoles of the formula I, it is not given patentable weight. See MPEP § 2111.02 and 37 CFR 1.75(c).

The examiner suggests amending or cancelling the claim, to overcome this objection.

Claim 5 is objected to because the recitation of an intended use for a compound must result in a structural difference in the compound, in order to be further limiting. In the instant claim, the intent is to use a substituted benzimidazole of the formula I, as a selective inhibitor of JAK-3 kinase. Since the intended use of a substituted benzimidazole of the formula I, as a selective inhibitor of JAK-3 kinase, fails to result in a structural difference to the substituted benzimidazoles of the formula I, it is not given patentable weight. See MPEP § 2111.02 and 37 CFR 1.75(c).

The examiner suggests amending or cancelling the claim, to overcome this objection.

Allowable Subject Matter

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, AU 1624